REMARKS/ARGUMENT

As described in the opening paragraphs of the specification, a SERM acts to control and regulate the estrogenic impact on tissues and organs which respond to i.e. are sensitive to, estrogen. The invention involves administering an effective amount of the SERM to control such estrogenic impact and then additionally administering another agent. Claim 1 has been appropriately amended to so state. As to claims 4 and 10-13, the Examiner's recognition that a word had been left out was correct and this has been remedied above.

In light of the foregoing amendments, it is respectfully submitted that the rejection under 35 U.S.C. 112 can now be withdrawn.

A supplemental election of species has been required with respect to the agent which exhibits progestogenic activity. In response, applicant selects levo-norgesterol (page 8, lines 6-7).

The early continued examination and allowance of this application is respectfully solicited.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Asst. Commissioner for Patents, Washington, D.C. 20231, on June 28, 2001:

Edward A. Meilman
Name of applicant, assignee or Registered Representative

Edward A. Meilman
Signature

June 28, 2001
Date of Signature

EAM:dmk:mgs

Respectfully submitted,

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APPENDIX B

VERSION WITH MARKINGS TO SHOW CHANGES MADE
37 C.F.R. § 1.121(b)(iii) AND (c)(ii)

CLAIMS:

1. In a method of hormone replacement therapy in a host by administering an effective amount of a selective estrogen receptor modulator to the host to control and regulate estrogenic impact on [specific] estrogen sensitive tissues and organs, the improvement which comprises additionally administering an agent which exhibits progestogenic activity to the host in an amount effective to modulate the side effects of the selective estrogen receptor modulator.

4. The method of claim 1 wherein the agent which exhibits progestogenic activity is an antiprogestin.

10. The method of claim 1 wherein the agent which exhibits progestogenic activity expresses both androgenic and progestogenic activity.

11. The method of claim 10 wherein the agent which exhibits progestogenic activity comprises the combination of an androgen and a progestin.

12. The method of claim 10 wherein the agent which exhibits progestogenic activity is a single material which expresses both activities.

13. The method of claim 12 wherein the agent which exhibits progestogenic activity is danazol or levonorgestrel.